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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,766	02/18/2000	Shlomo Ben-Haim	BIO-95	8645

7590

06/04/2002

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EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 06/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/506,766

Applicant(s)

BEN-HAIM ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The Applicant amended independent claims 1, 12, 16, 35, 42 and 47 to overcome the prior art of record. The amended claims now include "non-contact electrodes linearly arranged along a longitudinal axis of the (catheter) body". A new grounds of rejection is presented below.

Claim Rejections - 35 USC § 103

2. Claims 1-3, 7, 9, 10, 12, 13, 15-18, 22, 24, 25, 32-37, 39-45 and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US5718241) in view of Goldreyer (US 5385146).

Ben Haim et al. disclose a method and apparatus to treat arrhythmias with ablation using one or more catheters (abstract). The tip of the catheter contains an electrode which can function at a site in the heart to sense electrical cardiac activity, to act as an antenna to deliver radio-frequency energy to perform ablation of tissue, or to deliver stimuli for pacing the heart (c 11, ll 28-35). The electromagnetic location system in the tip of the catheter can contain between one and ten antennas to define the location of the tip area of the catheter (c 11, ll 49-59). In figure 16, a tip electrode (105) and additional electrodes (106) are disclosed. The receiving antennas are located near the distal tip of the catheter (c 12, ll 41-47). Ben-Haim et al. disclose the claimed invention except for the electrodes being non-contact electrodes linearly arranged along a longitudinal axis of the catheter body.

Goldreyer discloses a catheter to sense extremely localized intracardiac electrical patterns. Referencing figures 1 and 2, the catheter (10/32) includes a stimulating tip (14) and non-contact electrodes (34-46) shown to be 14 electrodes, read to be about 16 electrodes (c 5, ll

6-12). Goldreyer teaches an embodiment where the electrodes are non-contact (c 2, ll 10-11) and are linearly arranged along a longitudinal axis of the catheter body to enable simultaneous sensing and ablation and/or pacing activity (c 1, ll 55-59).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, and provide electrodes being non-contact electrode linearly arranged along a longitudinal axis of the catheter body as taught by Goldreyer to enable simultaneous sensing and ablation and/or pacing activity so accurate and discrete mapping of the electrophysiologic activation within the heart is achieved (c 1, l 63 – c 2, l 4).

3. Claims 4-6, 14, 19-21, 26-31, 38, 46 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US5718241) and Goldreyer (US 5385146) in view of Martinelli (US 6104944). As discussed in paragraph 2 of this action, modified Ben-Haim et al. disclose the claimed invention except for providing six degrees of location information using locations sensors in a proximate and a distal position relative to the electrode array.

Martinelli discloses a system and method for navigating a multiple electrode catheter and teaches that it is known to use two or more navigated electrode elements (N1-Nn), read as location sensors, between multiple virtually navigable electrode elements (E1-En), read as an array of non-contact electrodes (column 4, line 66 – column 5, line 8 and column 5, lines 24-33) to define the position of electrodes in a domain such as a chamber of the heart (column 4, lines 63-66). Martinelli teaches the use of electromagnetic field sensors as the navigated electrode elements to provide navigational location information (column 6, lines 18-32). These navigated electrode elements provide orientation data and position coordinate data, read as the six degrees

of location information (column 6, lines 54-64 and column 8, lines 29-65), to establish the location of the virtually navigated electrodes and enable accurate mapping of the heart.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, providing six degrees of location information using location sensors in a proximate and a distal position relative to the electrode array as taught by Martinelli to enable accurate mapping of the heart so arrhythmia producing cardiac tissue is identified and can be ablated.

4. Claims 8, 11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim (US 5718241) and Goldreyer (US 5385146) in view of Swanson et al. (US 6171306). As discussed in paragraph 2 of this action, modified Ben-Haim discloses the claimed invention except for the distal tip contact electrode being a bipolar electrode. Swanson et al. disclose an ablation catheter and teach that it is known to use a bipolar distal tip electrode to ablate the cardiac tissue (figure 5, and column 7, lines 11-14). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, with a bipolar distal tip electrode as taught by Swanson et al. to utilize the electrodes in the device, the tip and the array electrodes, to ablate the tissue, eliminating the need for the addition of an external indifferent electrode (column 7, lines 17-20). Utilizing a bipolar configuration also provides a more targeted ablating stimulus enabling more precise ablation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Art Unit: 3762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
5/31/02

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GEORGE R. EVANISKO
PRIMARY EXAMINER

5/31/02